HFI-35 4/27/00

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-42

March 27, 2000

Than Thi Vu, Vice-President and Owner
N.T.T. Seafood, Inc.
7328 Jefferson Avenue
Southport, Florida 32409

Dear Mrs. Vu:

We inspected your firm, located at 7328 Jefferson Avenue, Southport, FL on August 11, 1999 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov.

The deviations were as follows:

> You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm could not provide a HACCP plan for fresh crabmeat to control the food safety hazard of pathogen growth and toxin formation.
>
> You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records for each day's production of fresh crabmeat at your facility.

In addition, you are required to retain all of the records required by the seafood HACCP regulation at your processing facility for official review and copying. However your HACCP plan, most of your process monitoring records and all of your sanitation monitoring records were not available for our review during the above inspection.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please provide in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a copy of your HACCP plan, sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4733.

Sincerely,

Marie A. Urban

Marie A. Urban
Acting Director, Florida District